IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES and WISCONSIN ALUMNI RESEARCH FOUNDATION,	)	
Plaintiffs,	)	C.A. No. 12-234-GMS
v.	)	
HOSPIRA, INC.,	)	
Defendant.	)	

DEFENDANT HOSPIRA, INC.'S ANSWER,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Hospira, Inc. ("Hospira"), through its attorneys, hereby submits this Answer, Affirmative Defenses and Counterclaims to the Complaint filed by Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF").

NATURE OF THE ACTION

1. Hospira admits that the Complaint purports to state an action for infringement of U.S. Patent No. 5,597,815 ("the '815 patent") arising out of Hospira's New Drug Application filing. Hospira otherwise denies the allegations of Paragraph 1.

THE PARTIES

2. On information and belief, Hospira admits the allegations in Paragraph 2.

3. On information and belief, Hospira admits that WARF is a corporation having its principal place of business at 614 Walnut Street, Madison, Wisconsin. Hospira

otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and therefore denies same.

4. Hospira admits that it is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

JURISDICTION AND VENUE

5. Hospira admits that the Complaint purports to state an action for patent infringement and declaratory judgment arising under the United States Patent Laws, 35 U.S.C. §§ 1 *et seq*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Hospira admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Hospira otherwise denies the allegations of Paragraph 5.

6. Hospira does not contest personal jurisdiction for purposes of this action only.

7. Hospira does not contest venue for purposes of this action only.

FACTS PERTINENT TO ALL COUNTS

8. Hospira admits that the '815 patent indicates on its face that it is entitled "Prevention of Hyperphosphatemia in Kidney Disorder Patients" and that it issued on January 28, 1997. Hospira also admits that the '815 patent indicates on its face that WARF is the assignee and that the named inventors are Hector F. DeLuca and Edward Slatopolsky. Hospira further admits that what appears to be a copy of the '815 patent was attached to the Complaint as Exhibit A. Hospira otherwise denies the allegations of Paragraph 8.

9. Hospira admits that the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the expiration date of the '815 patent as July 13, 2015. Hospira otherwise denies the allegations of Paragraph 9.

10. Hospira admits that the Orange Book lists the '815 patent with respect to NDA No. 020-819 for Zemplar®. Hospira otherwise denies the allegations of Paragraph 10.

11. Hospira admits that the Orange Book indicates that a six month pediatric exclusivity is associated with respect to NDA No. 020-819 for Zemplar®. Hospira otherwise denies the allegations of Paragraph 11.

12. Hospira admits that it submitted NDA No. 201-657 to the FDA under the provisions of § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), seeking approval to introduce into interstate commerce Paricalcitol injectable drug products in 2 mcg/ml, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations. Hospira otherwise denies the allegations of Paragraph 12.

13. Hospira admits that it sent a letter to Abbott dated June 7, 2011 notifying Abbott that Hospira had filed NDA No. 201-657 containing a certification under §505(b)(2)(A)(iv) of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv), ("Paragraph IV Certification"), and stating that U.S. Patent No. 6,136,799 ("the '799 patent") and U.S. Patent No. 6,361,758 ("the '758 patent") are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, offer for sale or sale of the [paricalcitol injectable] drug product[s] described in Hospira's NDA."

14. Hospira admits that Abbott filed a Complaint (C.A. No. 11-648-GMS, D.I. 1) against Hospira on July 21, 2011 alleging infringement of the '799 patent and the '758 patent.

To the extent that Paragraph 14 states conclusions of law or background information as opposed to allegations, no response is required from Hospira. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 and therefore denies same.

15. On information and belief, Hospira admits the allegations in Paragraph 15.

16. Hospira admits that an actual, justiciable controversy exists within this jurisdiction regarding the infringement of the '799 patent and the '758 patent. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 and therefore denies same.

17. Hospira admits that it sent a letter to Abbott and WARF dated July 26, 2011 notifying Abbott and WARF that Hospira had submitted a Paragraph IV Certification with respect to the '497 patent, and stating that the '497 patent is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, offer for sale or sale of the [paricalcitol injectable] drug product[s] described in Hospira's NDA."

18. Hospira admits that Plaintiffs filed a Complaint (C.A. No. 11-795-GMS, D.I. 1) against Hospira on September 9, 2011 alleging infringement of the '497 patent. To the extent that Paragraph 18 states conclusions of law or background information as opposed to allegations, no response is required from Hospira. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18 and therefore denies same.

19. On information and belief, Hospira admits the allegations in Paragraph 19.

20. Hospira admits that an actual, justiciable controversy exists within this jurisdiction regarding the infringement of the '497 patent. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20 and therefore denies same.

21. Hospira admits that it received Plaintiffs' letter regarding the '815 patent listing on December 7, 2011. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 and therefore denies same.

22. Hospira admits that it has not provided Abbott and WARF with a Paragraph IV Notice addressing the '815 patent. Hospira otherwise denies the allegations of Paragraph 22.

23. Hospira denies the allegations of Paragraph 23.

24. Hospira admits that it seeks FDA marketing approval under § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2) of paricalcitol injection drug products for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5. Hospira admits that this use is the only FDA authorized use of paricalcitol injection. Hospira denies the other allegations in Paragraph 24.

25. Hospira admits that its proposed product label states that secondary hyperparathyroidism is characterized by an elevation in parathyroid hormone (PTH) associated with inadequate levels of active vitamin D hormone. Hospira admits that its proposed product label states that in a diseased kidney, the activation of vitamin D is diminished, resulting in the rise of PTH, subsequently leading to secondary hyperparathyroidism. Hospira admits that

paricalcitol is a synthetically manufactured analog of calcitrol, the metabolically active form of vitamin D, and that Vitamin D and paricalcitol have shown to reduce parathyroid hormone levels by inhibiting PTH synthesis and secretion. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 and therefore denies same.

26. Hospira is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 and therefore denies same.

27. Hospira admits that its proposed product label describes that vitamin D and paricalcitol have been shown to reduce parathyroid hormone level by inhibiting PTH synthesis and secretion. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 and therefore denies same.

28. Hospira admits that its proposed label indicates paricalcitol injection for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5. Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 and therefore denies same.

29. Hospira admits that its proposed product label states that secondary hyperparathyroidism is characterized by an elevation in parathyroid hormone (PTH) associated with inadequate levels of active vitamin D hormone. Hospira admits that its proposed product label states that the decreased levels of calcitrol ($1,25(OH)_2D_3$) and resultant elevated PTH levels, both of which often precede abnormalities in serum calcium and phosphorous, affect bone turnover rate and may result in renal osteodystrophy. Hospira denies the other allegations in Paragraph 29.

30. Hospira admits that the specification of the '815 patent states that, "[s]econdary hyperparathyroidism is a universal complication in patients with chronic renal failure." ('815 patent, col. 1, lines 26-27). Hospira admits that the specification of the '815 patent states that, "19-nor-1,25-$(OH)_2D_2$, is an ideal tool for the treatment of secondary hyperparathyroidism and renal osteodystrophy. This analog (19-nor-1,25-$(OH)_2D_2$) has been shown to be as effective as 1,25-$(OH)_2D_3$ in suppressing PTH in vitro and in rats with chronic renal insufficiency. In addition, the effects on calcium and phosphorous are minimal, allowing the use of larger doses of this compound to suppress secondary hyperparathyroidism." ('815 patent, col. 9, lines 64-67; col. 10, lines 1-6). Hospira otherwise is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 and therefore denies same.

31. Hospira denies the allegations of Paragraph 31.

32. Hospira admits that it is aware of the '815 patent and that its proposed label will direct physicians and healthcare professionals to prescribe paricalcitol injection for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease Stage 5. Hospira denies the other allegations in Paragraph 32.

33. Hospira denies the allegations of Paragraph 33.

34. Hospira denies the allegations of Paragraph 34.

35. Hospira admits that this Court has subject matter jurisdiction for the purposes of this action only.

COUNT 1
INFRINGEMENT OF THE '815 PATENT

36. Hospira repeats and incorporates herein by reference its response to Paragraphs 1-35.

37. Hospira denies the allegations of Paragraph 37.

38. Hospira denies the allegations of Paragraph 38.

39. Hospira denies the allegations of Paragraph 39.

COUNT 2
DECLARATORY JUDGMENT AS TO THE '815 PATENT

40. Hospira repeats and incorporates herein by reference its response to Paragraphs 1-39.

41. Hospira admits that it filed NDA No. 201-657. Hospira otherwise denies the allegations of Paragraph 41.

42. Hospira denies the allegations of Paragraph 42.

43. Hospira denies the allegations of Paragraph 43.

44. Hospira denies the allegations of Paragraph 44.

HOSPIRA'S AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The manufacture, use, offer for sale, sale and/or importation into the United States of Paricalcitol injectable products described in NDA No. 201-657 does not and will not infringe any valid and enforceable claim of the '815 patent.

THIRD AFFIRMATIVE DEFENSE

The claims of the '815 patent are invalid for failing to meet one or more of the requirements for patentability of Title 35 of the United State Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims and the relief sought by Plaintiffs, in relation to the claims of the '815 patent, are barred in whole or in part by the doctrine of equitable estoppel.

FIFTH AFFIRMATIVE DEFENSE

The relief sought by Plaintiffs in relation to the claims of the '815 patent is barred in whole or in part by the doctrine of laches.

COUNTERCLAIMS OF HOSPIRA, INC.

Hospira, Inc. ("Hospira") asserts the following counterclaims against Abbott Laboratories ("Abbott") and Wisconsin Alumni Research Foundation ("WARF"):

THE PARTIES

1. Hospira is a corporation organized and existing under the laws of the state of Delaware having its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

2. On information and belief, Abbott is a corporation organized under the laws of the State of Illinois, having its headquarters and principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. On information and belief, WARF is a corporation organized under the laws of the State of Wisconsin, having its principal place of business at 614 Walnut Street, Madison, Wisconsin 53726.

JURISDICTION AND VENUE

4. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the United State Patent Laws, 35 U.S.C. § 101 *et seq.*

5. This court has subject matter jurisdiction based upon 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Abbott and WARF are subject to personal jurisdiction in this judicial district and have consented to personal jurisdiction by commencing an action for patent infringement in this judicial district, as set forth in their Complaint.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

8. On January 28, 1997, U.S. Patent No. 5,597,815 ("the '815 patent") issued. The '815 patent is entitled "Prevention of Hyperphosphatemia in Kidney Disorder Patients" and states on its face that the assignee is WARF.

9. On information and belief, the FDA approved NDA No. 020-819 for the marketing of paricalcitol, 5 mcg/ml, injectable for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure on April 17, 1998.

10. On information and belief, the FDA approved NDA No. 020-819 for the marketing of paricalcitol, 2 mcg/ml, injectable for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure on February 1, 2000.

11. On information and belief, U.S. Patent Nos. 5,246,925 and 5,587,497 ("the '925 patent" and "the '497 patent) were listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") at the time the FDA approved NDA No. 020-819, as covering Paricalcitol injectable products, which are marketed by Abbott under the brand name Zemplar®.

12. The '925 patent issued on September 21, 1993. The '925 patent is entitled "19-nor-Vitamin D compounds for use in treating hyperparathyroidism" and states on its face that the assignee is WARF.

13. On information and belief, the user code listed for the '925 patent is U-314.

14. User code U-314 defines a method of treating hyperparathyroidism which comprises suppressing parathyroid activity.

15. On April 17, 1998, the product label for Zemplar® indicated the use of Paricalcitol in the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

16. On information and belief, Abbott has commercially manufactured, marketed and sold this drug product under the trade name Zemplar® in the United States since in or about April 1998.

17. On September 2, 2005, the product label for Zemplar® was modified and indicated the use of Paricalcitol in the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.

18. Hospira submitted NDA No. 201-657 to the FDA under the provisions of § 505(b)(2) of the FFDCA, 21 U.S.C. § 355(b)(2), seeking approval to introduce into interstate commerce Paricalcitol injectable drug products in 2 mcg/ml, 5 mcg/ml, and 10 mcg/2 ml (5 mcg/ml) formulations.

19. On information and belief, in or about December 2011, Abbott requested that the '815 patent should be among the listed patents for Zemplar® in the Orange Book, and the '815 patent was subsequently listed for Zemplar® in the Orange Book.

20. On information and belief, the user code listed for the '815 patent is U-1195.

21. User code U-1195 defines the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5, which may result in renal osteodystrophy, while avoiding hyperphosphatemia.

22. On information and belief, the product label for Zemplar® does not indicate the use of Paricalcitol in the prevention and treatment of renal osteodystrophy, while avoiding hyperphosphatemia.

CASE AND CONTROVERSY

23. An actual, justiciable controversy exists within this jurisdiction regarding the infringement of the '815 patent by Hospira's proposed generic Paricalcitol injectable products, as evidenced by Abbott and WARF's Complaint and Abbott's listing of the '815 patent in the Orange Book with respect to Abbott's NDA No. 020-819.

COUNT 1

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '815 PATENT

24. Hospira repeats and incorporates herein by reference its Counterclaim Paragraphs 1-23.

25. The manufacture, use, offer for sale, sale, and/or importation of the Paricalcitol injectable products described in NDA No. 201-657 does not and will not infringe any valid, enforceable claim of the '815 patent.

COUNT 2

DECLARATORY JUDGMENT OF INVALIDITY OF THE '815 PATENT

26. Hospira repeats and incorporates herein by reference its Counterclaim Paragraphs 1-25.

27. The claims of the '815 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 1 *et seq.*

COUNT 3

MANDATORY INJUNCTION ORDERING ABBOTT TO REQUEST DELISITING OF THE '815 PATENT FROM THE ORANGE BOOK

28. Hospira repeats and incorporates herein by reference its Counterclaim Paragraphs 1-27.

29. Under 21 U.S.C. § 355(c)(3)(D)(ii), Hospira seeks a mandatory injunction ordering Abbott to immediately request that the FDA delist the '815 patent from the Orange Book for NDA 020-819 (Zemplar®).

30. The '815 patent does not meet the requirement of 21 U.S.C. §§ 355(b)(1)-(b)(2), and the regulations thereunder, including without limitation, 21 C.F.R. § 314.53(b). It is therefore improper for Abbott to list the '815 patent in the Orange Book.

31. Under 21 U.S.C. § 355(c)(3)(D)(ii)(I), Hospira is entitled to a mandatory injunction ordering Abbott to immediately request the FDA to delist the '815 patent from the Orange Book.

WHEREFORE, Hospira respectfully prays for judgment:

(a) Dismissing Abbott and WARF's Complaint with prejudice and denying Abbott and WARF all relief requested in their Complaint and any relief whatsoever;

(b) Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of the Paricalcitol injectable products described in NDA No. 201-657 does not and will not infringe any valid and enforceable claim of the '815 patent;

(c) Declaring that each claim of the '815 patent is invalid;

(d) Declaring that the '815 patent is not properly listed in the Orange Book and entering a mandatory injunction ordering Abbott to immediately request the FDA to delist the '815 patent from the Orange Book;

(e) Enjoining Abbott, WARF, and their officers, agents, employees, and all persons acting in concert or participation with them, from asserting the '815 patent against Hospira or any of its customers, manufacturers, and distributors;

(f) Finding this to be an exceptional case and awarding Hospira attorney fees pursuant to 35 U.S.C. § 285;

(g) Awarding Hospira its costs and expenses; and

(h) Granting Hospira such other and further relief as the Court may deem just and equitable.

March 19, 2012

BAYARD, P.A.

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